



Serial No.: 08/266,154  
Art Unit: 1806

### III. DETAILED ACTION

15. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

16. The filing of new claims 78-95 in the amendment filed 6/27/94 is acknowledged.

17. Applicant's limitation of the claims to recite the production of antibodies in lymphoid cell lines obviates the rejection under § 112. In addition, applicant's explanation of the apparent inconsistencies in the 131 declaration are sufficient. The fact that the reagent was replaced and the experiments were subsequently successful establishes that the said success was reproducible. Accordingly, said rejection is withdrawn.

18. Claims 39-41, 43-48, 54-55, 57-58, 60-69, and 71-95 are rejected under 35 U.S.C. § 103 as being unpatentable over Cabilly (L,R, or 2A) or Boss (2b) in view of Gillies(S).

Applicant's arguments filed 6/27/94 have been fully considered but they are not deemed to be persuasive.

Rejections are maintained for reasons of record, stated in papers 5, 7, and 10, mailed November 29, 1988, May 24, 1989, and September 25, 1990.

The amendment and response filed 6/27/94 set forth the following grounds of traversal. The first asserts that insufficient predictability existed at the priority date to allow coexpression of two antibody chains. Applicants urge that the Cabilly references do not have a teaching of specific coexpression of genes in a mammalian system and that Cabilly's yield was not nearly as good as that in the instant case. Gillies is criticized for the alleged failure to actually show functional antibody. In addition, the Gillies patent allegedly fails to assess the yield of a functional antibody. Only raw, unassembled protein is shown.

These arguments have been considered but are not deemed persuasive. The argument concerning Cabilly is not considered persuasive because of the aforementioned specific teaching of producing antibodies in mammalian cells. While applicants are correct in characterizing Cabilly's disclosure as non-enabling for myeloma cell production, Cabilly is only used to teach double transfection. Gillies shows the production of antibodies in myeloma cells. Moreover, Gillies teaches the production of proteins in a yields approaching wild type. Therefore, such yields are considered approximating 100% in comparison to applicant's 32%. Accordingly, applicant's argued unexpected yields are not considered as such. As far as applicant's

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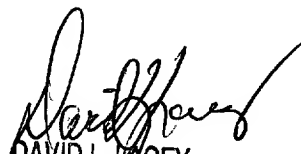
regarding the fact that Gillie's yield is of unassembled protein, such is simply not supported by Gillies. Applicants have not pointed out the statement in Gillies where the routineer would learn that Gillies' protein is not assembled. Absent such a clear disclosure to the contrary, it is more reasonable to assume that Gillies' disclosed yield is functional. Otherwise, Gillies would not be producing the protein. The protein/antibody is of no use when it is not functional. Accordingly, ~~Applicants~~ the rejection is maintained and no claim is allowed.

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Examiner Nisbet whose telephone number is (703) 308-4204 from 9:00 am to 5:00 pm weekdays with the exception of alternating Fridays. If the examiner cannot be reached, the supervisor may be contacted at phone number (703)308-3535.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

TMN

October 31, 1994

  
DAVID L. LACEY  
SUPERVISORY PATENT EXAMINER  
GROUP 130  
